

**APPLICANTS' INTERVIEW SUMMARY RECORD**

Applicants' representative thanks Examiner Marx for the courtesy of the telephonic interviews in connection with the above-identified application. Pursuant to MPEP section 713.04, Applicants submit the following statements of the substance of telephonic interviews held between Examiner Irene Marx and Applicants' representative Margaret Brivanlou in connection with the above-identified application.

**December 27, 2004**

As stated in the Examiner's Statement, Examiner Marx attempted to telephone Applicants' representative on December 27, 2004 and Applicants' representative's secretary informed Examiner Marx that Applicants' representative was out of the office.

**December 29, 2004**

On December 29, 2004, Applicants' representative telephoned Examiner Marx who indicated that the Amendment filed November 2, 2004 did not put the claims in condition for allowance and that an Advisory Action had been mailed.

**January 20, 2005**

A telephonic interview between Applicants' representative Margaret Brivanlou and Examiner Marx was held on January 20, 2005, to discuss the outstanding issue set out in the Advisory Action dated December 30, 2004. Examiner Marx indicated that deletion of the phrase "and cancers and neoplasias of the gastrointestinal tract" from claim 32 would address the stated concern. Examiner Marx also indicated that, for the claims to be in condition for allowance, Applicants should cancel claim 34, drawn to HIV-associated Chronic Diarrhea. In particular, Examiner Marx stated that she did not believe the specification enabled treatment of HIV-associated Chronic Diarrhea using the claimed method. Examiner Marx agreed that data from clinical trials could address this concern.

**January 21, 2005**

NYJD: 1560875.1

A telephonic interview between Applicants' representative Margaret Brivanlou and Examiner Marx was held on January 21, 2005, in which Applicants' representative pointed out that the Applicants had previously addressed the Examiner's concern that claim 34 was not enabled in an Amendment under 35 U.S.C. § 1.111 filed July 6, 2004 ("July 2004 Amendment") and that the Examiner had not maintained this rejection in the subsequent Office Action dated September 17, 2004. In particular, Applicants' representative pointed out that Applicants had submitted in the July 2004 Amendment results from phase II and phase III clinical trials that demonstrated that the claimed proanthocyanidin polymer composition was effective in the treatment of HIV-associated Chronic Diarrhea. Examiner Marx replied that Applicants should provide a written response to her objection to claim 34.

**REMARKS**

After entry of this amendment, claims 21-38, 40, 75, and 76 will be pending.

Applicants have amended claim 32 to delete the phrase "cancers and neoplasias of the gastrointestinal tract." This amendment is made without prejudice to pursue the subject matter in a related application and introduces no new matter.

**I            Rejection of Claim 32 Under 35 U.S.C. 112, Should be withdrawn**

Claim 32 is rejected under 35 U.S.C. § 112. The Examiner alleges in the Advisory Action that the distinction cannot be readily ascertained between what is deemed to constitute a "cancer" as opposed to a "neoplasia." Without agreeing with the Examiner and solely for expediting prosecution, claim 32 has been amended to comply with Examiner's suggestion in the telephone interview of January 20, 2005 by deleting the phrase "cancers and neoplasias of the gastrointestinal tract." In view of the foregoing, Applicants respectfully request that this rejection under 35 U.S.C. § 112, be withdrawn.

**II            Claim 34 is Enabled**

As discussed above in the Applicants' Interview Summary Record, the Examiner has orally rejected claim 34 as not enabled. Applicants respectfully point out that in the Office Action dated January 8, 2004, the Examiner rejected, *inter alia*, claim 34 as not enabled by the specification as the specification was only enabling for traveler's diarrhea and not for diarrheas associated with other indications, such as, HIV-Associated Chronic Diarrhea (see pages 2-3). As summarized below, in the July 2004 Amendment, Applicants addressed this rejection. In view of the data and arguments presented by Applicants, the Examiner dropped the rejection in the September 17, 2004 Office Action.

In response to the Examiner's oral request in the telephone interview of January 21, 2005, Applicants highlight where in the record they responded to this rejection. Applicants respectfully point out that Applicants had submitted data from clinical trials in

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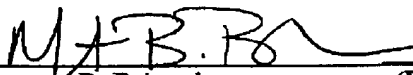
patients with HIV-Associated Chronic Diarrhea as Exhibit C of the July 2004 Amendment (a copy of which is provided for the Examiner's convenience). Exhibit C at Figures 4 and 6-7 provides data demonstrating that, in studies of patients with HIV-Associated Chronic Diarrhea, oral administration of enterically coated tablets or beads of isolated aqueous soluble proanthocyanidin polymer composition of Croton produced a clinically relevant decrease in stool weight. In addition, administration of the claimed composition resulted in decrease in stool frequency and significant improvement in gastrointestinal symptoms, especially urgency, particularly in patients with at least one watery stool and associated urgency at baseline. (See discussion on page 11 of the July 2004 amendment). Accordingly, prior to the Final Rejection of the claims in the September 17, 2004 Office Action, Applicants had already put evidence on the record showing that HIV-Associated Chronic Diarrhea can be ameliorated using the claimed methods. Thus, there is evidence already in the record that claim 34 is enabled.

### Conclusion

Applicants believe that they have addressed all the issues outstanding in connection with the present application. Accordingly, reconsideration and allowance of the present application in view of the above amendments and arguments is respectfully requested. Applicants respectfully request that the Examiner call the undersigned if any questions or issues remain.

Date: January 28, 2005

Respectfully submitted,

  
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